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ABSTRACT

Embodiments of the invention are directed to a method of estimating the physical stability of a protein formulation. A particular embodiment of the invention places the protein formulation under an agitational stress that causes the protein to aggregate at an accelerated rate. In one embodiment, the change in protein aggregation is monitored spectroscopically using Thioflavin-T. Embodiments of the invention then utilize a survival curve analysis to ascertain the relative physical stability of the different protein formulations under study. This method was used to develop novel surfactant-stabilized insulin formulations in a rapid, cost efficient manner, thus illustrating the utility of the inventive method to the discovery and development of pharmaceutical protein formulations.